

JAN 19 2001

Section 2 Page 2 of 3

K003484

**ScImage, Inc. Netra™ Workstation and NetraMD™ Software - 510(K) Premarket Notification****510(k) SUMMARY of Safety and Effectiveness**

This following summary is provided as part of this Premarket Notification in compliance with and based on the format set forth in the Final Rule as published in the Federal Register, December 14, 1994. (See 21 CFR § 807.92)

**(1) Submitters Name / Contact Person:**

ScImage, Inc.  
4916 El Camino Real  
Suite 200  
Los Altos, California 94022

Contact Person: Michael Peter, Director of Operations  
Tel.: (650) 694-4858  
Fax: (650) 694-4859  
E-mail: mike\_peter@scimage.com

Date prepared: November 8, 2000

**(2) Name of device:**

**Trade Name:** Netra™ Workstation and NetraMD™ Software  
**Common Name:** Medical image workstation system, PACS.  
**Classification Name:** §892.2050 Picture archiving and communications system.

**(3) Identification of predicate device:**

Manufacturer	Device	510(k) Number
ScImage, Inc.	Netra™ Workstation and NetraMD™ Software	K960911
Vital Images, Inc.	Vitrea 1.3 Image Processing Software	K990442
Vital Images, Inc.	VSCORE with EKG Sign	K001682
Vital Images, Inc.	VOXEL VIEW	K953259

**(4) Description of the device:**

The Netra™ Workstation and NetraMD™ Software Medical Image Management system is a multi-modality comprehensive three- and four-dimensional image presentation software system intended for acceptance, transfer, display, storage and digital processing of medical images.

NetraMD combines reconstruction and display algorithms for medical image analysis in the familiar Microsoft Windows environment. NetraMD offers full compliance with

DICOM 3.0 file formats and JPEG Standards that permit transfer of image data with medical imaging equipment.

The Workstation features PC Computer based hardware and Microsoft Windows NT/2000 operating system and incorporates SMPTE Test Pattern files.

(5) A statement of the intended use of the device:

The Netra™ Workstation and NetraMD™ Software Medical Image Management system is intended for acceptance, transfer, display, storage and digital processing of medical images.

Its hardware components may include digitizers, workstations, communications devices, computers, video monitors, magnetic, optical disk, or other digital data storage devices and hardcopy devices.

The software components provide functions for performing operations related to image manipulation, enhancement, compression or quantification.

(6) Predicate Device Comparison:

The Netra™ Workstation and NetraMD™ Software is substantially equivalent to similar features in the predicate devices and has the same intended uses and technological characteristics. The new features included in the modified software do not affect the safety or effectiveness of the device.

The modified device complies with the following voluntary standards as "Special Controls" to ensure safe and effective use:

- ACR/NEMA Digital Imaging and Communications in Medicine (DICOM) standard
  - Joint Photographic Experts Group (JPEG) standard
  - Society of Motion Picture and Television Engineers (SMPTE) Test Pattern
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JAN 19 2001

Michael Peter  
Director of Operations  
SciImage, Inc.  
4916 El Camino Real  
Los Altos, CA 94022

Re: K003484  
Netra™ Workstation and NetraMD™ Software System  
Dated: November 8, 2000  
Received: November 9, 2000  
Regulatory class: II  
21 CFR 892.2050/Procode: 90 LLZ

Dear Mr. Peter:

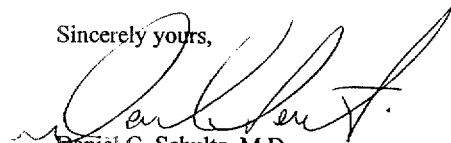
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

  
Daniel G. Schultz, M.D.  
Captain, USPHS  
Acting Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure (s)

**2.0 FDA Indication for use form.**

510(k) Number (if Known): \_\_\_\_\_

Device Name: Netra™ Workstation and NetraMD™ Software**Indications For Use:**

The Netra™ Workstation and NetraMD™ Software Medical Image Management system is intended for acceptance, transfer, display, storage and digital processing of medical images.

Its hardware components may include digitizers, workstations, communications devices, computers, video monitors, magnetic, optical disk, or other digital data storage devices and hardcopy devices.

The software components provide functions for performing operations related to image manipulation, enhancement, compression or quantification.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)Prescription Use ☒  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices510(k) Number K003484

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CONFIDENTIAL